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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,272	04/06/2001	James M. Lipton	259/058	6351

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PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
CHISM, BILLY D	

ART UNIT	PAPER NUMBER
1654	19

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,272	LIPTON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *5,6,10-19,24,25 and 29-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-9,20-23 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 11,16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This Office Action is in response to Paper No. 18, filed 12 June 2003, wherein Applicants elected without traverse Group I of Set 1, claims 1-4, 7-9, 20-23 and 26-28 and SEQ ID NO:1 and glucocorticoid as an anti-inflammatory. Claims 1-38 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 7-9, 20-23 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 and 20-21 are indefinite for being drawn to non-elected subject matter, i.e., sequences that are not part of the elected invention.

Claims 1 and 20 are rejected for the indefinite recitation of the term "dermatological disorders" wherein the term is broad and the term is vague regarding the metes and bounds of the possible disorders.

Claims 8-9 and 27-28 are rejected for indefinite and vague recitation of "medicinal properties" wherein the metes and bounds are not clear. The Examiner suggests combining claim 8 with claim 9 and combining claim 27 with claim 28 for a definite claimed invention.

Claims 3-4, 7, 22-23 and 26 are rejected for depending from rejected claims.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claims indicates that these claims are drawn to a genus, i.e., dermatological disorders.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such

as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are only a small number of single species of the claimed genus disclosed that are within the scope of the claimed genus, *i.e.* contact dermatitis and psoriasis. The disclosure of a single disclosed species or just a few may provide an adequate written description of a genus when the species disclosed are representative of the genus. However, the present claimed genus encompasses numerous species that are not further described. There is substantial variability among the species.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises all possible species of dermatological disorders. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

4. Claims 20-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an agent for treating psoriasis and contact dermatitis utilizing a KPV composition, does not reasonably provide enablement for an agent which prevents psoriasis and contact dermatitis utilizing a KPV. In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. *The nature of the invention and the breadth of the claims*: In the instant case, applicants are claiming a composition that is an agent for "preventing" dermatological disorders. The nature of the invention is of a pharmaceutical for the treatment of a disease, i.e. dermatological disorders. As stated, however, the claim asserts that the composition is capable of preventing such disorders, or to keep from happening.

2. *The state of the prior art and the predictability or lack thereof in the art*: The state of the art does not teach the absolute prevention of dermatological disorders, merely that the symptoms of the disease, such as psoriatic lesions (specification page 19, line 11), may be treated. Thus, any claim to the prevention of such dermatological disorders is highly unpredictable given the current state of the art. For example, Cutluli et al. 2000 (Antimicrobial Effects of alpha-MSH peptides. Journal of Leukocyte Biology, Vol. 67, No. 2 pages 233-239) teach that the KPV significantly inhibits *S. aureus* colony formation but does not teach the prevention.

3. *The amount of direction or guidance present and the presence or absence of working examples*: Furthermore, applicant states that the invention may be used in the prevention of dermatological disorders (specification page 7, lines 1-2) but does not provide examples as such. Whereas examples are given for the amelioration of contact dermatitis and psoriasis, prevention is not taught.

4. *The quantity of experimentation needed, and the level of the skill in the art*: Because neither the prior art nor the current application provide sufficient guidance to one of even ordinary skill in the art as to the prevention of dermatological disorders, the quantity of experimentation for such a claim is considered to be undue and thus, not enabled.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutuli et al.

Cutuli *et al.* teach the antimicrobial influences of KPV against *Staphylococcus aureus*, bacteria that can be found in the skin.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-4 and 7-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7 and 10-11 of copending Application No. 10/023,287 ('287) in view of Cutuli *et al.* This is a provisional obviousness-type double patenting rejection.

'287 teach a composition for treatment of pruritis comprising KPV or a biologically active equivalent, a shampoo (liquid, oil, cream, etc...) with an anti-inflammatory (glucocorticoid, i.e., beclomethasone diproproionate and prednosolone) (Claims 1-3, 7 and 10-11). The present application teaches a composition for treatment of dermatological disorders comprising KPV or a biologically active equivalent, a carrier (liquid, ointment, cream, etc...) with an anti-inflammatory (glucocorticoid, i.e., beclomethasone diproproionate and prednosolone) (Claims 1-4 and 7-9).

Cutuli *et al.* teach the use of KPV for colony inhibition of *Staphylococcus aureus*, bacteria found on the skin. The present application claims a composition comprising KPV for treatment of dermatological disorders (Claim 1-2).

'287 teaches the composition for treating a species which anticipates the genus of dermatological disorders, especially in light of Cutuli *et al.* teaching the inhibitory affects of KPV as an antimicrobial against bacteria known to cause dermatological disorders in humans.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutuli *et al.* Cutuli *et al.* discuss the importance of combining the antimicrobial affects of KPV with the corticosteroids (glucocorticoids) since formulations of corticosteroids are known to detrimentally reduce killing of pathogens. Thus, the combining of the two would work to reduce inflammation as well as affect microbial activity at the site, i.e., KPV reducing *Staphylococcus aureus* on the skin. The use of carriers and their formulations in the art is commonly known for pharmaceutical compositions.

Conclusions

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 703-306-5815. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism
25 August 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER